

**IN THE UNITED STATES DISTRICT COURT OF THE
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

**IN RE: DIGITEK
PRODUCTS LIABILITY LITIGATION**

MDL NO. 1968

THIS DOCUMENT RELATES TO ALL CASES

**PLAINTIFFS' RESPONSE IN OPPOSITION TO MOTION TO DISMISS COUNT FIVE
OF THE MASTER CONSOLIDATED COMPLAINT FOR INDIVIDUALS**

Plaintiffs, in opposition to the Defendants' Motion To Dismiss Count Five of the Master Consolidated Complaint for Adoption by Individuals ("Master Complaint"), submit the following Memorandum.

I. INTRODUCTION

The Master Complaint asserts claims against Actavis Totowa, Inc., Actavis, Inc., Actavis Elizabeth, Inc., Mylan, Inc., Mylan Pharmaceuticals, Inc., Mylan Bertek Pharmaceuticals, Inc., and UDL Laboratories, Inc. for, *inter alia*, product liability, negligence, and negligence *per se* arising from the manufacturing, sale, and distribution of Digitek. Count Five of the Master Complaint alleges negligence *per se* against all defendants for failing to meet the standards of care set by the relevant provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301 *et seq.* ("FDCA") and the regulations promulgated thereunder. (Master Complaint, ¶95).

Defendants have filed the present motion to dismiss the negligence *per se* count on the grounds that it is an attempt to improperly assert a private cause of action under the FDCA. Plaintiffs submit that Count Five of the Master Complaint is not an attempt to assert a private cause of action under the FDCA, but rather the well accepted use of the FDCA and the

regulations promulgated thereunder to establish a baseline standard of care to govern the Plaintiffs' state law causes of action.

II. ARGUMENT

Plaintiffs may use the FDCA and the regulations promulgated thereunder to establish a baseline standard of care for the Plaintiffs' state law causes of action.

Although the Defendants are correct that the FDCA does not provide a private cause of action, the Defendants have misconstrued the Master Complaint. The Plaintiffs are not attempting to enforce the FDCA or assert its violations as a private cause of action, but rather are using the FDCA to establish the baseline standard of care for their state law causes of action. The courts have made it clear that the FDCA may be used to establish the standard of care for state law claims. *See Ezagui v. Dow Chemical Corp.*, 598 F.2d 727 (2d Cir. 1979); *Orthopedic Equipment Co. v. Eutsler*, 276 F.2d 455 (4th Cir. 1960); *Grove Fresh Distributors v. Flavor Fresh*, 720 F. Supp. 714 (N.D. Ill. 1989); *Allen v. Delchamps, Inc.*, 624 So. 2d 1065 (Ala. 1993); *Axen v. American Home Products Corp.* 974 P.2d 224 (Or. Ct. App. 1999), *modified on other grounds*, 981 P.2d 340 (Or. Ct. App. 1999), *rev. denied*, 994 P.2d 124 (Or. 1999), *cert. denied*, 120 S. Ct. 979 (Or. 2000).

To further display the extent to which the Defendants have misinterpreted the Plaintiffs' use of negligence *per se*, the Defendants' own memorandum quotes the Third Circuit in *In Re Orthopedic Bone Screws Products Liability Litigation*, 193 F.3d 781 (3rd Cir. 1999) for the proposition that the Plaintiffs may not invoke violations of the FDCA to state a cause of action. In stating that the plaintiffs may not assert the violations as a cause of action, the Third Circuit implicitly acknowledges that the use of the statutes to establish standard of care is appropriate, stating "the theory of per se liability advanced by the plaintiffs here is quite different. Plaintiffs do not invoke the statutory violations to prove defendants' liability for a separate underlying tort,

but instead contend the violation themselves form a cause of action.” *Id.* at 791. The Plaintiffs in this case have made it clear that they are invoking the Defendant’s violations of the FDCA to prove the Defendant’s liability for separate underlying torts by establishing the standard of care and not, as the Defendants suggest, to form a private cause of action. As even the case law cited by the Defendants acknowledges that the Plaintiffs’ use of the Defendants’ violations of the FDCA in this case is proper, the Defendants’ motion to dismiss is without merit.

III. CONCLUSION

The Plaintiffs in this case have asserted that the FDCA serves as a baseline standard of care which governs the Plaintiffs’ state law causes of action. As the foregoing case law makes clear, the Plaintiffs are entitled to establish the standard of care through the FDCA and the regulations promulgated thereunder. The Defendants have presented this Court with absolutely zero case law that would support otherwise; therefore, the Defendants’ motion to dismiss Count Five of the Master Complaint should be denied.

Dated: May 19, 2009

Respectfully submitted,

On Behalf of the Plaintiffs’ Steering
Committee

s/Fred Thompson, III Esq.
Fred Thompson, III, Esq.
Motley Rice, LLC
28 Bridgeside Blvd.
Mt. Pleasant, SC 29464
Co- Lead Counsel

Carl N. Frankovitch, Esq.
Frankovitch, Anetakis, Colantonio & Simon
337 Penco Road
Weirton, WV 26062
Co- Lead Counsel

Harry F. Bell, Jr., Esq.
Bell & Bands PLLC
P. O. Box 1723
Charleston 25326
Co- Lead and Liaison Counsel

Plaintiffs' Steering Committee:

Andres F. Alonso, Esq.
Parker, Waichman, Alonso LLP
111 Great Neck Road
Great Neck, New York 11021

K. Camp Bailey, Esq.
Bailey Perrin Bailey
Suite 2100
440 Louisiana Street
Houston, TX 77002-4206

Harry F. Bell, Jr., Esq.
Bell & Bands PLLC
P. O. Box 1723
Charleston, West Virginia 25326

Robert J. Binstock, Esq.
Reich & Binstock
Suite 1000
4265 San Felipe
Houston, TX 77027

Robert Blanchard, Esq.
Levin, Papantonio, Thomas,
Mitchell, Echsner & Proctor, P.A.
316 South Baylen Street, Suite 600
Pensacola, FL 32502

Lester L. Levy, Esq.
Wolf Popper LLP
845 Third Avenue
New York, NY 10022

Peter A. Miller, Esq.
The Miller Firm LLC
The Sherman Bldg.
108 Railroad Avenue
Orange, VA 22960

Ashley L. Ownby, Esq.
180 North Ocoee Street
P. O. Box 176
Chattanooga, TN 37364-0176

David M. Peterson, Esq.
Peterson & Associates, P.C.
Park Plaza Building, Suite 107
801 West 47th Street
Kansas City, MO 64112-1253

Frank Mario Pitre, Esq.
Cotchett, Pitre & McCarthy
Suite 200
840 Malcolm Road
Burlingame, CA 94010

Frank Mario Pitre, Esq.
Cotchett, Pitre & McCarthy
Suite 200
840 Malcolm Road
Burlingame, CA 94010

Ed Blizzard, Esq.
Blizzard, McCarthy & Nabers LLC
Suite 1710
440 Louisiana
Houston, TX 77002

John R. Climaco, Esq.
Climaco, Lefkowitz, Peca, Wilcox
& Garofoli Co., LPA
55 Public Square, Suite 1950
Cleveland, OH 44113

C. Brooks Cutter, Esq.
Kershaw, Cutter & Ratinoff LLP
401 Watt Avenue
Sacramento, CA 95864

Carl N. Frankovitch, Esq.
Frankovitch, Anetakis, Colantonio & Simon
337 Penco Road
Weirton, WV 26062

Daniel N. Gallucci, Esq.
RodaNast, P.C.
801 Estelle Drive
Lancaster, PA 17601

G. Erick Rosemond, Esq.
Hissey Kientz, L.L.P
9442 Capital of Texas Highway N.
Suite 400
Austin, TX 78759

Shelly A. Sanford, Esq.
Sanford Pinedo LLP
2016 Bissonnet Street
Houston, TX 77005-1647

J. Paul Sizemore, Esq.
Giardi Keese
1126 Wilshire Boulevard
Los Angeles, CA 90017

Fred Thompson, III, Esq.
Motley Rice, LLC
28 Bridgeside Blvd.
Mt. Pleasant, SC 29464

Teresa Toriseva, Esq.
Toriseva Law
1446 National Road
Wheeling, WV 26003

Stacy K Hauer, Esq.
Zimmerman Reed
651 Nicollet Mall, Suite 501
Minneapolis , MN 55402-4123

Scott Wm. Weinstein, Esq.
Morgan & Morgan, P.A.
Suite 600
12800 University Drive
P. O. Box 9504
Fort Myers, FL 33906

CERTIFICATE OF SERVICE

I hereby certify that on May 19, 2009, I electronically filed the foregoing “Response in Opposition to Defendants’ Motion to Dismiss Count Five of the Master Consolidated Complaint for Individuals” with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

s/Fred Thompson, III Esq._____
Fred Thompson, III, Esq.
Motley Rice, LLC
28 Bridgeside Blvd.
Mt. Pleasant, SC 29464
Co- Lead Counsel